PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 701039-54481	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2005/000714	International filing date *(day/month/year)* 10 January 2005 (10.01.2005)	Priority date *(day/month/year)* 09 January 2004 (09.01.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant CHILDREN'S MEDICAL CENTER COPORATION		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 10 July 2006 (10.07.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Athina Nickitas-Etienne e-mail: pt04@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
DAVID S. RESNICK
NIXON PEABODY LLP
100 SUMMER STREET
BOSTON, MA 02110-2131

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	01 JUN 2005
Applicant's or agent's file reference 701039-54481	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US05/00714	10 January 2005 (10.01.2005)	09 January 2004 (09.01.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): 436/63, 64, 174; 530/350, 385, 386, 387.1, 387.7, 387.9, 388.1 and US Cl.: G01N 1/00, 33/48; C07K 1/00, 14/00, 17/00; A61K ; C07K 1/00, 14/00, 16/00, 17/00

Applicant

CHILDREN'S MEDICAL CENTER CORPORATION

1. This opinion contains indications relating to the following items:

- [x] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [x] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [ ] Box No. VII — Certain defects in the international application
- [ ] Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703) 305-3230

Authorized officer
Alana M. Harris, Ph.D.
Telephone No. 571-272-1600

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/00714

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/00714

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 17-19	YES
	Claims 1-16	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-19	NO
Industrial applicability (IA)	Claims 1-19	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-16 lack novelty under PCT Article 33(2) as being anticipated by Roy et al. (The Journal of Biological Chemistry 279(49): 51323-51330, December 3, 2004). Roy teaches the detection of urinary ADAM 12 in samples from breast cancer patients and controls analyzed by immunoblot, see abstract. ADAM 12 protein levels were higher in urine from breast cancer patients than in control urine. Median levels of ADAM 12 in urine significantly increases with disease progression, see page 51324, column 1, first paragraph; bridging paragraph of pages 51325 and 51326; page 51329, column 2, first two sentences of last paragraph. Western blot analysis was conducted using labeled proteins and chemiluminescence, page 51324, column 2, Western...section.

Claims 17-19 lack an inventive step under PCT Article 33(3) as being obvious over Claims 1-16 lack novelty under PCT Article 33(2) as being anticipated by Roy et al. (The Journal of Biological Chemistry 279(49): 51323-51330, December 3, 2004). The teachings of Roy are presented above. Although Roy et al. does not teach a kit for detecting ADAM 12 in a urine sample comprising a container, at least one antibody and directions for use a scientist would have been inclined to package these components, as well as other reagents that would aid in cancer diagnosis for convenience.